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KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			ROBINSON, HOPE A	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/558,937	<b>Applicant(s)</b> NUNN, MILES ANDREW	
	<b>Examiner</b> HOPE A. ROBINSON	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6,7,9-16,18-20,29,30,41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,13,14,18-20,29,30,41 and 42 is/are rejected.
- 7) ☒ Claim(s) 6,7,9-12,15 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application Status***

1. The Amendment filed on September 16, 2009 is acknowledged.

### ***Claim Disposition***

2. Claims 41-42 have been added. Claims 1, 6-7, 9-16, 18-20, 29-30 and 41-42 are pending and are under examination.

### ***Sequence Compliance***

3. This application complies with the sequence rules based on the sequence listing provided on September 16, 2009.

### ***Drawing***

4. The drawings filed on September 16, 2009 are accepted by the examiner.

### ***Claim Objection***

5. Claims 1, 6-7, 9-16, 18 and 29-30 are objected to because of the following informalities:

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For clarity and precision of claim language, it is suggested that claim 1 is amended to read, "An isolated complement inhibitor polypeptide ~~[[derived]]~~ obtained from a haematophagous arthropod that inhibits the classical complement pathway and the alternative complement pathway by inhibiting cleavage of C5 by classical and alternative C5 convertases, wherein the isolated complement inhibitor polypeptide ~~[[is a protein having]]~~ has at least ~~[[90]]~~95% sequence identity to ~~[[a protein comprising]]~~ the amino acids 19 to 168 ~~[[of the amino acid sequence]]~~ of SEQ ID NO: 2.

For clarity it is suggested that claim 6 is amended to read, "The isolated complement inhibitor polypeptide ~~[[according to]]~~ of claim 1, ~~[[which]]~~ wherein said isolated complement inhibitor polypeptide inhibits cleavage of C5 by binding to C5".

For clarity it is suggested that claim 7 is amended to read, "The isolated complement inhibitor polypeptide ~~[[according to]]~~ of claim 6, wherein said isolated complement inhibitor polypeptide is complexed with C5".

For clarity and precision of claim language, it is suggested that claim 9 is amended to read, "The isolated complement inhibitor polypeptide ~~[[according to]]~~ of claim 1, wherein said haematophagous arthropod is a tick".

For clarity and precision of claim language, it is suggested that claim 10 is amended to read, "The isolated complement inhibitor polypeptide ~~[[according to]]~~ of claim 9, wherein said tick is *Ornithodoros moubata*".

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For clarity it is suggested that claim 11 is amended to read, "The isolated complement inhibitor polypeptide [[according to]] of claim 10, comprising the amino acids 19 to 168 [[of the amino acid sequence]] of SEQ ID NO: 2".

For clarity it is suggested that claim 12 is amended to read, "The isolated complement inhibitor polypeptide [[according to]] of claim 10, comprising [[amino acids 1 to 168 of]] the amino acid sequence of SEQ ID NO: 2".

For clarity and precision of claim language, it is suggested that claim 13 is amended to read, "[[The]]An isolated complement inhibitor polypeptide that inhibits the classical pathway and alternative complement pathways, wherein said complement inhibitor is:

a) a protein comprising the amino acids 19 to 168 [[or amino acids 1 to 168 of the amino acid ]] of SEQ ID NO:2;

b) a protein comprising the amino acid sequence of SEQ ID NO: 2;

[[b]]c [[a homologue of a]] the protein [[as defined in]] of a or b having at least 95% sequence identity [[thereto]] to SEQ ID NO:2; or

c) [[an active]] a fragment of [[said a protein as defined in a) above]] the complement inhibitor polypeptide of SEQ ID NO:2, wherein said [[active]] fragment comprises six cysteine residues that are spaced relative to each other at a distance of 32 amino acids apart, 62 amino acids apart, 28 amino acids apart, 1 amino acid apart, and 21 amino acids apart as arranged from the amino terminus to the carboxyl terminus of SEQ ID NO:2, wherein said [[active]] fragment inhibits cleavage of C5 by classical and alternative C5 convertases. See also **claim 14** which has the similar language.

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For clarity and precision of claim language, it is suggested that claim 15 is amended to read, "The isolated complement inhibitor polypeptide [[according to]] of claim 14 ,wherein said isolated complement inhibitor polypeptide [[which]] inhibits cleavage of C5 by directly binding to C5".

For clarity and precision of claim language, it is suggested that claim 16 is amended to read, "The isolated complement inhibitor polypeptide [[according to]] of claim 15 , wherein said isolated complement inhibitor polypeptide is complexed with C5".

For clarity it is suggested that claim 18 is amended to read, "A fusion protein comprising the isolated complement inhibitor polypeptide [[according to]] of claim 1, wherein said isolated complement inhibitor polypeptide [[that]] is genetically or chemically fused to [[one or more peptides or polypeptides]] a glutathione-5-transferase, a beta-galactosidase or a polyhistidine tag".

For clarity it is suggested that claim 29 is amended to read, "A composition comprising the isolated complement inhibitor polypeptide [[according to]] of claim 1 [[or a fusion protein thereof],]] in conjunction with a [[pharmaceutically acceptable]] carrier".

For clarity it is suggested that claim 30 is amended to read, "The composition [[according to]] of claim 29, [[further comprising]] wherein said carrier is an adjuvant".

Correction is required.

### ***Claim Rejections - 35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 13-14, 18-20, 29-30 and 41-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to an isolated complement inhibitor polypeptide ...wherein said complement inhibitor polypeptide has at least 90% identity to a protein comprising amino acids 19 to 168 of the amino acid sequence of SEQ ID NO:2 (see for example claim 1)" or any homologue having a structure that is 95% identical to SEQ ID NO: 2 (see for example claim 13) or any active fragment with the cysteine spacing provided in item c of claim 13 for example and a fusion protein comprising the isolated complement fused to an unlimited amount of peptides and polypeptides (see for example claim 18). The claimed invention encompasses a genus of structures not adequately described.

No correlation is made between structure and function. The claims lack adequate written description as they are defined by function only, having no structural limitation. Therefore, the skilled artisan cannot envision the detailed chemical structure of the polypeptides, thus, claims reciting said polypeptide lacks adequate written description.

The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. The claimed genus of polypeptides could include non-functional proteins or proteins with a different function than the one described. Therefore, the genus of claimed polypeptides encompasses widely variant species. Based on the unlimited variations contemplated one skilled in the art would at best expect a protein that is different or at worst a protein that is not functional.



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The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480

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F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents" of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or

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disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case is discussed below.

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

7. Claims 1, 13-14, 18-20, 29-30 and 41-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the protein set forth in SEQ ID NO: 2, does not reasonably provide enablement for any homologue/fragment of SEQ ID NO:2 or any fusion segments fused to SEQ ID NO:2 or a fragment/homologue thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue.

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These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

The amount of experimentation required to practice the claimed invention is undue as the claims encompass an unspecified amount of complement inhibitor proteins; fusion peptides/polypeptides; and homologues/ fragments of SEQ ID NO:2 absent any correlation between structure and function. The instant specification does not demonstrate or provide guidance as to what the structure of the protein will be once modified or if said protein will be functional or exhibit the same properties or characteristics as the native protein. In the instant application, the partial structure in the form of the recited percent identity is insufficient to determine a chemical structure for the variants encompassed in the claims. Additionally, there is no data provided demonstrative of a particular portion of the structure that must be conserved.

Therefore, the claims encompass variants/fragments that may not have any biological activity. The specification at paragraph [ 0021 ] sets forth that a homologue of the invention "...is meant to include reference to paralogues and orthologues of the OmCI sequence that is explicitly identified in FIG. 4, including, for example, the OmCI protein sequence from other tick species, including *Rhipicephalus appendiculatus*, *R. sanguineus*, *R. bursa*, *A. americanum*, *A. cajennense*, *A. hebraeum*, *Boophilus*

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*microplus*, *B. annulatus*, *B. decoloratus*, *Dermacentor reticulatus*, *D. andersoni*, *D. marginatus*, *D. variabilis*, *Haemaphysalis inermis*, *Ha. leachii*, *Ha. punctata*, *Hyalomma anatolicum anatolicum*, *Hy. dromedarii*, *Hy. marginatum marginatum*, *Ixodes ricinus*, *I. persulcatus*, *I. scapularis*, *I. hexagonus*, *Argas persicus*, *A. reflexus*, *Ornithodoros erraticus*, *O. moubata moubata*, *O. m. porcinus*, and *O. savignyi*. The term "homologue" is also meant to include the OmCI protein sequence from mosquito species, including those of the *Culex*, *Anopheles* and *Aedes* genera, particularly *Culex quinquefasciatus*, *Aedes aegypti* and *Anopheles gambiae*; flea species, such as *Ctenocephalides felis* (the cat flea); horseflies; sandflies; blackflies; tsetse flies; lice; mites; leeches; and flatworms". At paragraph [0024] of the specification it is disclosed that homologues include mutants containing amino acid substitutions, insertions or deletions from the wild type sequence. Note the laundry list of organisms provided by the specification, however, only an OMCI protein is demonstrated.

Moreover at paragraph [0025] of the specification it is disclosed that "fragments of the OmCI protein and of homologues of the OmCI protein are also provided by the invention. Included as such fragments are not only fragments of the *O. moubata* OmCI protein that is explicitly identified herein in FIG. 4, but also fragments of homologues of this protein, as described above". Due to the large quantity of experimentation necessary to generate the infinite number of variants/fragments recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue experimentation

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would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

Predictability of which potential changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (for example, expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, for example, multiple substitutions. In this case, the necessary guidance has not been provided in the specification. Therefore, while it is known in the art that many amino acid substitutions are possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited, as certain positions in the sequence are critical to the protein's structure/function relationship. It is also known in the art that a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many cases. For example, various sites or regions directly involved in binding activity and in providing the correct three-dimensional spatial orientation of binding and active sites can be affected (see Wells, *Biochemistry*, vol. 29, pages 8509-8517, 1990). The instant specification provides no guidance/direction as to which regions of the protein would be tolerant of modifications and which would not, and it provides no working examples of any variant sequence that is encompassed by the claims. It is in no way

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predictable that randomly selected mutations, such as deletions, substitutions, additions, etc., in the disclosed sequences would result in a protein having activity comparable to the one disclosed. As plural substitutions for example are introduced, their interactions with each other and their effects on the structure and function of the protein are unpredictable. The skilled artisan would recognize the high degree of unpredictability that all the fragments/variants encompassed in the claims would retain the recited function.

The state of the prior art provides evidence for the high degree of unpredictability as stated above. Seffernick et al. (J. Bacteriology, vol. 183, pages 2405-2410, 2001) disclose two polypeptides having 98% sequence identity and 99% sequence identity, differing at only 9 out of 475 amino acids (page 2407, right column, middle and page 2408, Fig. 3). The polypeptides of Seffernick et al. are identical along relatively long stretches of their respective sequences (page 2408, Fig. 3), however, these polypeptides exhibit distinct functions. The modifications exemplified in the Seffernick et al. reference is small compared to those contemplated and encompassed by the claimed invention.

The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims. Furthermore, while recombinant and mutagenesis techniques are known in the art, it is not routine in the art to screen large numbers of mutated proteins where the expectation of obtaining similar activity is unpredictable based on the instant disclosure. The amino acid sequence of a protein determines its structural and functional properties, and

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predictability of what mutations can be tolerated in a protein's sequence and result in certain activity, which is very complex, and well outside the realm of routine experimentation, because accurate predictions of a protein's function from mere sequence data are limited, therefore, the general knowledge and skill in the art is not sufficient, thus the specification needs to provide an enabling disclosure.

The working examples provided do not rectify the missing information in the instant specification pertaining to the claimed variant. The nature and properties of this claim is difficult to ascertain from the examples provided as one of skill in the art would have to engage in undue experimentation to construct the variants of the claimed invention and examine the same for function.

The specification does not provide support for the broad scope of the claims, which encompass an unspecified amount of variants/fragments of the polypeptides. The claims broadly read on any fragment thereof for the given sequences (SEQ ID NO: 2). At issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in



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the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to construct and test variants/homologues of the claimed invention would constitute undue experimentation. Making and testing the infinite number of possible variants to find one that functions as described is undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 13-14 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claims 13-14 lack clear antecedent basis for "The isolated compliment", the claim should be amended to read "An isolated compliment" as these are independent claims.

### ***Response to Arguments***

9. Applicant's comments have been considered in full, however, are not persuasive. Note that the rejections of record under 35 USC 112, first paragraph remains and a new rejection under 35 USC 112, second paragraph has been instituted. Withdrawn rejections/objections will not be discussed herein as applicant's comments are moot.

Regarding the rejection under 35 USC 112, first paragraph rejection, applicant state that the claims have been amended to recite for example 95% that the protein comprises six cysteines and the relative spacing. However, this argument is not persuasive because claim 1 for example does not recite 95%, the claims are drawn to 90% identity which means that approximately 15 amino acid residues could vary between residues 19 and 168. It is noted that claims 13 and 14 recite 95%, however, that limitation is not present in claim 1. Moreover, claims 13 and 14 are directed to a homologue of for example amino acid residues 19-168 of SEQ ID NO:2. In addition, the claims are directed to an active fragment comprises six cysteines and the relative spacing is provided, and said structure is relative to the recited 19-168 residues as well as the full length structure. Further, the claims are drawn to a fusion protein with an

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unlimited amount of peptides or polypeptides fused to amino acids 19-168. Thus the claimed invention encompasses a genus of structures, hence the rejections remain.

**Examiner Note:** The claimed invention has allowable subject matter as SEQ ID NO:2 and amino acid residues 19-168 of SEQ ID NO:2 are free of the art. It is suggested that the claims are amended as indicated above in the claim objections to bring the application in condition for allowance. It is also suggested that applicants cancel claims 19-20 and 41-42 in view of the amendments suggested above and to put the application in condition for allowance.

### ***Conclusion***

9. No claims are presently allowed.

10. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652

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